UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,624	08/15/2005	Christopher Anthony Morris	4501-1015	7843

466 7590 03/24/2009

YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER
SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,624	MORRIS ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/05, 7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, species A2 and A1 in the reply filed on 12/23/08 is acknowledged. Upon further consideration, however, the species election is WITHDRAWN.

Claim Objections

2. Claim 5 is objected to because of the following informalities: In claim 5 there is a typographical error wherein "p-casein" is recited instead of "β-casein." Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Elliott et al. (WO 96/14577).

Elliott et al. teach a method which comprises steps of (a) determining which cows of a herd produce milk containing β-casein having a proline at position 67 by testing genetic material of individual cows of the herd for the presence of DNA encoding β-casein having a histidine at position 67 or by testing milk produced by individual cows of the herd for the presence of β-

casein having a proline at position 67; (b) selecting cows that produce milk containing a β-casein having a proline residue at position 67; and (c) milking the selected cows. Namely, referring to page 2 of Elliott, they teach a method which comprises testing milk from identified cows for the presence of variants of β-casein, selecting those cows whose milk contains the preferable A2 variant of β-casein, milking those cows and recovering the milk (lines 21-26). Elliott et al. also teach that the cows or bulls can be genotyped directly using appropriate probes and polymerase chain reaction technology; this technology inherently tests genetic material of individual cows (p. 4, lines 23-24). Further, Elliott et al. teach that the milk should not contain the variant A1 (line 29). The A2 variant inherently has a proline residue at position 67, and the A1 variant inherently has a histidine at position 67. Elliott et al. are silent as to the intended use of reducing the level of saturated fatty acids relative to the level of unsaturated acids and the fatty acid composition of the obtained milk (as in claim 6). The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the prior art would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the prior art reference. Milk is a tissue containing or which contained nucleated cells. Therefore, the practice of the method taught by Elliott et al. inherently meets the limitations of the claimed methods.

5. Claims 1-7 and 9-10 rejected under 35 U.S.C. 102(e) as being anticipated by McLachlan (US 6,570,060).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McLachlan teaches a method which comprises steps of (a) determining which cows of a herd produce milk containing β-casein having a proline at position 67 by testing DNA or RNA (i.e. genetic material) from cells containing DNA or RNA obtained from one or more lactating bovines for the presence of DNA or RNA encoding β-casein A1 or A2 ; (b) selecting cows that produce milk containing a β-casein having a proline residue at position 67 (i.e. β-casein A2); and (c) milking the selected cows (Col. 3-4 of McLachlan). The A2 variant inherently has a proline residue at position 67, and the A1 variant inherently has a histidine at position 67. McLachlan is silent as to the intended use of reducing the level of saturated fatty acids relative to the level of unsaturated acids and the fatty acid composition of the obtained milk (as in claim 6). The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the prior art would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the prior art reference. McLachlan exemplifies the method by the testing of genetic material obtained from tail hairs which have follicles attached (Col. 15 and following). These contain nucleated cells. Therefore, the practice of the method taught by McLachlan meets the limitations of the claimed invention.

Double Patenting

6. Claims 1-7 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,570,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent anticipate the instantly claimed invention. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

7. Claims 1-7 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. US 7,094,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because anticipate the instantly claimed invention. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

8. Claims 1-7 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,157,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious in view of the claims of the issued patent. The issued patent teaches

selecting cows by determining the genotype of the cows and selecting those which produce milk which contains a β-casein variant with a proline at position 67 and does not contain variants with a histidine at amino acid 67, and further teaches that the genotyping is by using a probe and PCR. The claims do not expressly teach milking the cows to obtain the milk, but this would have been prima facie obvious to one of ordinary skill in the art, upon having practiced a method of selecting cows for their milk composition, in particular since the claims teach that the milk is not diabetogenic. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

9. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/515940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate each of the instant claims. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the copending claims would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method claimed in the copending application, and the claims of the copending application anticipate the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Tuesday or Wednesday, from 9:00 AM until 4:30 PM, and Thursday afternoon from 12:30 PM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

March 24, 2009